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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,413	11/21/2001	Nancy Allbritton	Q048	6314

7590

09/16/2003

Daniel L. Dawes
MYERS, DAWES & ANDRAS LLP
Suite 1150
19900 MacArthur Boulevard
Irvine, CA 92612

EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/16/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,413

Applicant(s)

ALLBRITTON ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-9,23,38 and 46-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-22,24-37 and 39-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 6.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traversal of Group III, claims 10-22 and 24-45, Species: electrophoresis, 2-D gel electrophoresis, microinjection, microlumen, a laser, in Paper No. 8, filed July 21, 2003 is acknowledged.
2. The traversal is on the ground(s) that the Office has failed to characterize the relationship between the Groups; therefore, the restriction requirement should be withdrawn. It is re-iterated that inventions in Groups I-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the apparatus of Group V may be utilized in the distinct usages as needed in Group I, which is an improvement in a method for assessing protein activity in a cell. As needed in Group II, which is a method for profiling signal transduction pathways. As needed in Group III, which is a method of detecting protein activity in a cell, portion of a cell, or group of cells. As needed in Group IV, which is an improvement in a method for detecting protein activity in a cell, portion of a cell, or group of cells. Alternatively, the apparatus could be used to analyze the differential expression of a gene as it is related to a lung cancer. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.
3. The requirement is still deemed proper and is therefore made FINAL.

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4. Claim 38 has been withdrawn due to being directed to subject matter that is not of the elected species.

5. Claims 10-22 and 24-37, and 39-45, Species: electrophoresis, 2-D gel electrophoresis, microinjection, microlumen, a laser are examined on the merits.

Priority

6. In order for the present application to receive benefit of priority for an invention to an earlier application, the earlier application (the parent or provisional application) must disclose the invention so as to be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112 regarding said invention. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994). The specific claimed subject matter of the present application was not disclosed in the priority document (US 6,156,576 A). Specifically the parent priority document does not disclose all of the embodiments such as the steps for detecting activity or the elected species of microinjection. Therefore, the claim for domestic priority under 35 U.S.C. §119(e) has been denied.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 12 and 13, line 2, recites the limitation "said external stimulus or stimuli". There is insufficient antecedent basis for this limitation in the claim.

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10. Claims 14 and 15, lines 1-2 recites the limitation "wherein compiling a tabulation of protein activity". There is insufficient antecedent basis for this limitation in the claim.

11. Specific to claim 16, lines 5-6, the terms "desired" and "undesired" causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a cellular response is being "desired" and "undesired" (fluorescent intensity or cell viability count).

Clarification of the metes and bounds of the instant claim is required.

CLAIM REJECTIONS - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 10-22 and 24-37, and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (1998) taken with Sims et al. (1998) in view of Magal (US 5,929,041 A) and Wright (US 5,639,656 A).

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15. Day et al. discloses a method of detecting protein activity in a cell, portion of a cell or group of cells comprising introducing the reporter molecules luciferase (Luc) and green fluorescent protein (GF) via a vector (Figure 1) into GH3 and Hela cells (page 848, column 3, lines 32-42 and page 850, column 1, lines 1-30). The reporter molecules are released for electrophoresis (page 850, column 1, lines 33-56). The reporter molecules are identified by fluorescence microscopy (laser as defined by Dictionary.com) (Figure 2) and electrophoresis by first boiling reporter molecule to terminate chemical reaction and by dilution of anti-GFP antibody to diminish chemical reaction (page 850, column 1, lines 33-56), as in instant claims 10, 17, 19-22, 27, 28, 33, and 37.

16. The cells were exposed to hygromycin and luciferin external stimuli prior to releasing the reporter molecules (page 582, lines 7-28), as in instant claims 12 and 13.

17. The chemical reaction is also terminated by adding cycloheximide (page 852, column 1, lines 23-30), as in instant claims 29-32.

18. The reporter molecule of Day et al. is a chimeric protein comprising of GFP and Luc (854, column 3, lines 1-11), as in instant claim 18.

19. However, Day et al. does not disclose the use of microinjection, microlumen, or 2-D electrophoresis for the method of detecting protein activity in a cell, portion of a cell or group of cells.

20. Magal discloses a method of using microlumen a means of presenting protein products (reporter molecules) from cochlear hair cells (column 30, lines 65-67).

21. Wright et al. discloses a method of identifying report molecules from cells by 2-D electrophoresis (column 16, line 64 to column 17, line 6), as in instant claims 39 and 40.

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22. Sims et al. discloses method of detecting protein activity in a cell, portion of a cell or group of cells by microinjecting labeled IP_3 at concentration of 100 nM into oocytes (Abstract etc.). The results are compiled in a tabulation of protein activity as directed to the reporter molecule, IP_3 , (page 4057, Table I), as in instant claims 11, 14-16, and 24-26.

23. The method of Sims et al. suggests the detection and quantification of at least 10 proteins for their activity; starting with several forms of 5-phosphatase to centruin- α and proteins involved in IP_3 degradative pathways (page 4052, column 2, lines 1-25), as in instant claims 41-45).

24. At various time points (0-300 seconds) the reactions are stopped, inositol phosphates are isolated and separated by HPLC (Figure 2 B), as in instant claims 34-36.

25. Day et al. suggests an improvement via recent advances in digital imaging systems for visualizing events as they occur with the living cell by detecting protein activity with reporter molecules (page 848, column 2, lines 1-6). The improvement suggested by Day et al. comprises detecting and releasing reporter molecules by protein isolation (pages 848-853, Materials and Methods §). Magal discloses a method of using microlumen as a means of presenting protein products (reporter molecules) from cochlear hair cells and photographed using a computer (column 32, lines 63-67). Wright et al. discloses a method of identifying report molecules from cells by 2-D electrophoresis (column 16, line 64 to column 17, line 6). Sims et al. discloses method of detecting protein activity in a cell, portion of a cell or group of cells by microinjecting labeled IP_3 (Abstract etc.). Thus, the improvement suggested by Day et al. is directly applicable to the methods of isolating reporter molecules for the detection of protein activity as taught by Magal, Sims et al., and Wright et al.

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26. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement suggested by Day et al. to use a method of detecting protein activity in a cell, portion of a cell or group of cells comprising introducing the reporter molecules wherein said method requires the limitations of electrophoresis, 2-D gel electrophoresis, microinjection, microlumen, and a laser. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of detecting protein activity in a cell, portion of a cell or group of cells comprising introducing the reporter molecules wherein said method requires the limitation of electrophoresis, 2-D gel electrophoresis, microinjection, microlumen, and a laser as taught by Day et al., Magal, Sims et al., and Wright et al.

CONCLUSION

27. NO CLAIM IS ALLOWED.

28. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

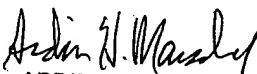
29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

31. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
9/13/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER